UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: April 26, 2019

SUBJECT: Efficacy Brace
EPA Reg. 777-99
DP Barcode: 450107
E submission # 34259

FROM: Lorilyn M. Montford
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Tajah Blackburn, Senior Scientist
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: 5/9/19

TO: Jacqueline Hardy, PM 34/Srinivas Gowda
Regulatory Management Branch II
Antimicrobials Division (7510P)

APPLICANT: Reckitt Benckiser, Inc.
Morris Corporate Center IV
399 Interspace Parkway
Parsippany, NJ 07054-0225

FORMULATION FROM LABEL:

Active Ingredients:	% by wt.
Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium saccharinate	0.10%
Ethanol	58.00%
Inert Ingredients	41.90%
Total	100.00%

I. BACKGROUND

Product Description (as packaged, as applied): Concentrated Spray

Submission type: Product Amendment

Requested action(s): Addition of several organisms to the product label. The applicant has requested to amend the product registration label to add soft surface (spot) disinfection (bactericidal) claims against *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa (*ATCC 15442*), and Salmonella enterica (*ATCC 10708*).*

Documents considered in this review:

- Letter from applicant to EPA dated November 14, 2018.
- Applications for Pesticide (EPA Form 8570-1) dated November 14, 2018.
- Data Matrix (EPA Form 8570-35) dated November 14, 2018.
- Formulator's Exemption Statement (EPA Form 8570-27), dated November 14, 2018.
- 3 efficacy studies (MRIDs 507267-01, 507267-02, and 507267-03).
- Proposed label dated November 13, 2018.
- Confidential Statement of Formula (EPA Form 8670-4) dated November 13, 2018.
- Additional organisms are required to be tested at the LCL. All product lots (2147-054, 2147-151, 2147-086) were tested at or below the lowest certified limit.

II. USE DIRECTIONS

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
(Read the entire label before using the product.)

(**To Unlock Cap:** Turn counterclockwise (1) (2) (clicks). Lock cap, after use.)

To (Disinfect)/(Sanitize) hard, non-porous surfaces and semi critical medical device or medical equipment surfaces): Preclean surface. (Hold can upright 6: to 8: from surface. Spray 3 to 4 seconds.) Leave (surface) wet for time indicated (above) (below) (in the box) (table)) to (sanitize) (and) disinfect.) Air dry. Rinse food contact surfaces (and toys) with (potable) water.

(To Sanitize/Disinfect (Soft Surfaces) (Fabrics): Spray until wet. DO NOT SATURATE. Leave for (30 seconds) to sanitize and for (9.5 minutes) (10 minutes) to disinfect. Air dry. (For difficult odors, repeat application.))

To Control/Eliminate odor-causing Bacteria on Soft Surfaces (Fabrics): Spray until wet. DO NOT SATURATE. Air dry. (For difficult odors, repeat application.)

III. AGENCY STANDARDS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surface sin hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product batches (tested at the lowest certified limit (LCL)), against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "hospital disinfectants", killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level for the AOAC Germicidal Spray Method. To support products labeled as "hospital disinfectants" conducted utilizing the "Use-Dilution Method", killing on 57 out of 60 carriers for *Staphylococcus aureus* and 54 out of 60 for *Pseudomonas aeruginosa* is required to provide effectiveness at the 95% confidence level.

IV. Brief Description of the Data

1. **MRID 507267-01, "Disinfectant Efficacy Testing in the Presence of Organic Soil". Test Organism: *Pseudomonas aeruginosa* (ATCC 15442) for BRACE, Formula 1178-172 (777-99), Lots #2147-054, #2147-086 and #2147-151. Study conducted at Accuratus Lab Services by Jamie Herzan, B.S. Study completion date – December 12, 2016. Project Number A21670.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. 2147-054, 2147-086 and 2147-151) of the product, BRACE, Formula 1178-172 (777-99)**,** were tested using Accuratus Protocol No. SRC99072816.CUST.1.PROP. The product was received ready-to-use as an aerosol spray. A 10 µL aliquot of a thawed, vortex mixed cryovial of stock culture was transferred to an initial 10 mL tube of synthetic broth, mixed and incubated for 24±2 hours at 36±1ºC. Following incubation, a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of synthetic broth (1st daily transfer). The final test culture was incubated for 48-54 hours at 36±1ºC. The test culture was vortex mixed (>3 seconds) and allowed to stand 10-15 minutes prior to use. The upper portion was removed and pooled in a sterile vessel and mixed. The culture was diluted by combining 10.0 mL of test organism suspension with 20.0 mL of sterile synthetic broth. A 1.0 mL aliquot of fetal bovine serum (FBS) was added to 19 mL of prepared culture to achieve a 5% organic soil load. Individual sterile 100% plain cotton weave fabric carriers (1 inch x 1 inch) were inoculated with 10 µL of the prepared culture in each corner and in the direct center of the carrier for a total of 50 µL of the test culture using a calibrated positive displacement micropipette. The inoculated carriers were dried for 30 minutes at 36±1ºC (36ºC) at 50% relative humidity. Carriers were used within 2 hours of drying. Using sterile forceps, each inoculated and dried fabric carrier was aseptically transferred to individual sterile treatment vessels with the inoculated side of the carrier facing upward, and the lids of each treatment vessel were replaced. Prior to treatment, the lids were removed, and the treatment vessels were tilted slightly to a ≤45º angle. Each test carrier was sprayed with the test substance, using staggered intervals, at a distance of 6-8 inches from the carrier surface for 3 seconds or until thoroughly wet (3 seconds used). The lids of the treatment vessels were replaced after

spraying the carriers. The carriers were exposed for 9.5 minutes at room temperature (19-20°C) at 48% relative humidity. Prior to the end of the exposure time, the lids were removed from the treatment vessels. At the end of the exposure time (within ±5 seconds) 70 mL of neutralizer (Letheen Broth + 0.75% Lecithin + 3.0% Tween 80) was added to each vessel using identical staggered intervals. The lids were replaced, and the treatment vessels were vortex mixed for 3-4 seconds. All subcultures were incubated for 48±2 hours at 36±1ºC. Following incubation, the subcultures were examined for the presence or absence of visible growth. Due to cloudiness of the neutralizing subculture medium prior to testing, the presence or absence of growth could not be determined visually. All subcultures were streaked to Tryptic Soy Agar + 5% Sheep's blood (BAP) and incubated at 36±1ºC for 1 day. The agar plates were examined for the presence or absence of visible growth. On 9/15/16, representative test subcultures showing growth on BAP plates were subcultured to BAP and Cetrimide Agar and incubated at 36±1ºC for 1 day. The resultant growth was visually examined, Gram stained and biochemically assayed to confirm or rule out the presence of the test organism. Controls included those for verification of the identity of the test culture, sterility, viability, neutralization confirmation, survivor counts/dried recovery control carriers, and inoculum count.

2. **MRID 507267-02, "Disinfectant Efficacy Testing in the Presence of Organic Soil". Test Organism: *Staphylococcus aureus* (ATCC 6538) for BRACE, Formula 1178-172 (777-99), Lots #2147-054, #2147-086 and #2147-151. Study conducted at Accuratus Lab Services by Jamie Herzan, B.S. Study completion date – December 12, 2016. Project Number A21673.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 2147-054, 2147-086 and 2147-151) of the product, BRACE, Formula 1178-172 (777-99)**,** were tested using Accuratus Protocol No. SRC99072816.CUST.3.PROP. The product was received ready-to-use as an aerosol spray. A 10 µL aliquot of a thawed, vortex mixed cryovial of stock culture was transferred to an initial 10 mL tube of synthetic broth, mixed and incubated for 24±2 hours at 36±1ºC. Following incubation, a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of synthetic broth (1st daily transfer). The final test culture was incubated for 48-54 hours at 36±1ºC. The test culture was vortex mixed (>3 seconds) and allowed to stand 10-15 minutes prior to use. The upper portion was removed and pooled in a sterile vessel and mixed. The culture was diluted by combining 5.0 mL of test organism suspension with 10.0 mL of sterile synthetic broth. A 0.70 mL aliquot of fetal bovine serum (FBS) was added to 13.3 mL of prepared culture to achieve a 5% organic soil load. Individual sterile 100% plain cotton weave fabric carriers (1 inch x 1 inch) were inoculated with 10 µL of the prepared culture in each corner and in the direct center of the carrier for a total of 50 µL of the test culture using a calibrated positive displacement micropipette. The inoculated carriers were dried for 30 minutes at 36±1ºC (36.5-36.6º C) at 47.7% relative humidity. Carriers were used within 2 hours of drying. Using sterile forceps, each inoculated and dried fabric carrier was aseptically transferred to individual sterile treatment vessels with the inoculated side of the carrier facing upward, and the lids of each treatment vessel were replaced. Prior to treatment, the lids were removed, and the treatment vessels were tilted slightly to a ≤45º angle. Each test carrier was sprayed with the test substance, using staggered intervals, at a distance of 6-8 inches from the carrier surface for 3 seconds or until thoroughly wet (3 seconds used). The lids of the treatment vessels were replaced after spraying the carriers. The carriers were exposed for 9.5 minutes at room temperature (20°C) at 50% relative humidity. Prior to the end of the exposure time, the lids were removed from the treatment vessels. At the end of the exposure time (within ±5 seconds) 70 mL of neutralizer (Letheen Broth + 0.75% Lecithin + 3.0% Tween 80) was added to each vessel using identical staggered intervals. The lids were replaced, and the treatment vessels were vortex mixed for 3-4 seconds. All subcultures were incubated for 48±2 hours at 36±1ºC. Following incubation, the subcultures were examined for the presence or absence of visible

growth. Due to cloudiness of the neutralizing subculture medium prior to testing, the presence or absence of growth could not be determined visually. All subcultures were streaked to Tryptic Soy Agar + 5% Sheep's blood (BAP) and incubated at 36±1ºC for 1 day. The agar plates were examined for the presence or absence of visible growth. Controls included those for verification of the identity of the test culture, sterility, viability, neutralization confirmation, survivor counts/dried recovery control carriers, and inoculum count.

3. **MRID 507267-03, "Disinfectant Efficacy Testing in the Presence of Organic Soil". Test Organism: *Salmonella enterica* (ATCC 10708) for BRACE, Formula 1178-172 (777-99), Lots #2147-054, #2147-086 and #2147-151. Study conducted at Accuratus Lab Services by Jamie Herzan, B.S. Study completion date – December 7, 2016. Project Number A21676.**

This study was conducted against *Salmonella enterica* (ATCC 10708). Three lots (Lot Nos. 2147-054, 2147-086 and 2147-151) of the product, BRACE, Formula 1178-172 (777-99)**,** were tested using Accuratus Protocol No. SRC99072816.CUST.5.PROP. The product was received ready-to-use as an aerosol spray. A 10 µL aliquot of a thawed, vortex mixed cryovial of stock culture was transferred to an initial 10 mL tube of synthetic broth, mixed and incubated for 24±2 hours at 36±1ºC. Following incubation, a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of synthetic broth (1st daily transfer). One additional daily transfer was prepared. The final test culture was incubated for 48-54 hours at 36±1ºC. The test culture was vortex mixed (>3 seconds) and allowed to stand 10-15 minutes prior to use. The upper portion was removed and pooled in a sterile vessel and mixed. The culture was diluted by combining 2.0 mL of test organism suspension with 14.0 mL of sterile synthetic broth. A 1.5 mL aliquot of fetal bovine serum (FBS) was added to 13.5 mL of prepared culture to achieve a 10% organic soil load. Individual sterile 100% plain cotton weave fabric carriers (1 inch x 1 inch) were inoculated with 10 µL of the prepared culture in each corner and in the direct center of the carrier for a total of 50 µL of the test culture using a calibrated positive displacement micropipette. The inoculated carriers were dried for 32 minutes at 36±1ºC (36.5-36.6ºC) and at 59.1% relative humidity. Carriers were used within 2 hours of drying. Using sterile forceps, each inoculated and dried fabric carrier was aseptically transferred to individual sterile treatment vessels with the inoculated side of the carrier facing upward, and the lid of each treatment vessel was replaced. Prior to treatment, the lids were removed, and the treatment vessels were tilted slightly to a ≤45º angle. Each test carrier was sprayed with the test substance, using staggered intervals, at a distance of 6-8 inches from the carrier surface for 3 seconds or until thoroughly wet (3 seconds used). The lids of the treatment vessels were replaced after spraying the carriers. The carriers were exposed for 9.5 minutes at room temperature (20°C) and 23% relative humidity. Prior to the end of the exposure time, the lids were removed from the treatment vessels. At the end of the exposure time (within ±5 seconds) 70 mL of neutralizer (Letheen Broth + 0.75% Lecithin + 3.0% Tween 80) was added to each vessel using identical staggered intervals. The lids were replaced, and the treatment vessels were vortex mixed for 3-4 seconds. All subcultures were incubated for 48±2 hours at 36±1ºC. Following incubation, the subcultures were examined for the presence or absence of visible growth. Due to cloudiness of the neutralizing subculture medium prior to testing, the presence or absence of growth could not be determined visually. All subcultures were streaked to Tryptic Soy Agar + 5% Sheep's blood (BAP) and incubated at 36±1ºC for 1 day. The agar plates were examined for the presence or absence of visible growth. Controls included those for verification of the identity of the test culture, sterility, viability, neutralization confirmation, survivor counts/dried recovery control carriers, and inoculum count.

V. RESULTS

MRID Number	Organism	Batch No.	No. of Carriers Exhibiting Growth/ Total No. Tested	Inoculum Count (CFU/mL)	Survivor Counts/Dried Recovery Control (Mean Log_{10} Density)
9.5 Minute Exposure Time (5% Soil Load)					
507267-01	*Pseudomonas aeruginosa* (ATCC 15442)	2147-054 2147-086 2147-151	0/60 0/60 0/60	2.9×10^8	5.81
507267-02	*Staphylococcus aureus* (ATCC 6538)	2147-054 2147-086 2147-151	0/60 0/60 0/60	1.04×10^8	6.59
9.5 Minute Exposure Time (10% Soil Load)[a]					
507267-03	*Salmonella enterica* (ATCC 10708)	2147-054 2147-086 2147-151	0/60 0/60 0/60	7.2×10^7	6.57

[a]10% soil load was inadvertently added – should have been 5%

VI. STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method	Contact Time	Soil load	Organism(s)	Data supports tested conditions (yes/no)
507267-01	Disinfection (bactericidal)	Soft, porous (cotton) surfaces	Spray, Ready to Use	9 min + 30 sec.	5%	• *Pseudomonas aeruginosa* (ATCC 15442)	Yes
507267-02				9 min + 30 sec.	5%	• *Staphylococcus aureus* (ATCC 6538)	
507267-03				9 min + 30 sec.	10%	• *Salmonella enterica* (ATCC 10708)	

The submitted efficacy data support the ready-to-use product, BRACE, as an effective disinfectant (bactericidal) spray against the following microorganisms on 100% cotton fabric in the presence of a 5% organic soil load for a 9 minute + 30 second contact time, at room temperature (19-20°C):

Pseudomonas aeruginosa (ATCC 15442) 507267-01
Staphylococcus aureus (ATCC 6538) 507267-02
Salmonella enterica (ATCC 10708;(10% soil load inadvertently used) 507267-03

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

VII. RECOMMENDATIONS

The label claims that the product, BRACE, a ready-to-use spray, is an effective disinfectant (for spot use) against the following bacteria on soft, 100% plain cotton weave fabric for a 9-minute + 30 second (10-minute) contact time in the presence of a 5% organic soil load:

Pseudomonas aeruginosa (ATCC 15442)
Staphylococcus aureus (ATCC 6538)
Salmonella enterica (ATCC 10708)

These claims are acceptable as they are supported by the submitted data.

LABEL RECOMMENDATIONS:

1. The applicant is requesting to bridge data from their existing product, EPA Reg. No. 777-127, for soft surface claims against additional bacteria and various viruses and fungi. The 777-127 product was tested against *S. aureus, P. aeruginosa*, and *S. enterica* using synthetic polyester blend carriers. This product, 777-99, was tested against *S. aureus, P. aeruginosa*, and *S. enterica* using a 100% cotton weave blend material to bridge to EPA

Reg. No. 777-127, ANDES. Consequently, claims are acceptable for the following microorganisms for BRACE at the designated contact time at RTU

Rhinovirus Type 39 (VR-340)	9.5-minute contact time
Influenza A virus (H1N1) (Strain: A/Swine/Iowa/15/30) (VR-333)	9.5-minute contact time
Trichophyton mentagrophytes (should be *Trichophyton interdigitale*)	9.5-minute contact time

2. On pages 3 and 5 of the proposed label, please remove the new phrase, “Our America’s favorite #1 most preferred brand (scent) fragrance”. This type of statement can be considered false and misleading.

3. On page 4 of the proposed label, please remove the statement, “4 people 1 toilet”. This statement suggests a heighten efficacy.

4. On page 4 of the proposed label, please remove the statement, “consumer preferred #1 voted favorite”. This statement is false and misleading.

5. On pages 4 and 5 of the proposed please remove the statement, “Deodorizes to Save you (your (Nose)”. This statement suggests a heighten efficacy.

6. On page 4 of proposed label, please remove the term, “chicken”. It is not explained how this word fits into the labeling claims.

7. On page 9 of the proposed label, **please remove the terms, “seconds/hours/days”** at the end of the phrase that begins, “Eliminates/Destroys/Neutralizes/Removes odors for up to “seconds/hours/days”. This phrase suggests continued or residual efficacy of the product.

8. On pages 9, 11 and throughout the entire label, please insert the phrase, “SPOT CLEANING” where soft surface disinfection is printed as this product is a spot disinfection cleaner for soft surfaces.

9. On page 11 of proposed label, top and bottom, please remove “**in 30 seconds**, and **“Disinfects in seconds**”. These claims are misleading. This claim is directly printed with the disinfection claims, “kills”. This time frame does not reflect the 10 -minute contact time for disinfectant claims.

10. On pages 15 and 26 of proposed label, please change “*Trichophyton mentagrophytes* to *Trichophyton interdigitale*. This organism name has been changed.

11. The **EMERGING VIRAL PATHOGEN CLAIM** on page 28 of the proposed label is considered acceptable since it only refers to hard, non-porous surfaces.

12. All others proposed label changes are considered acceptable.

13. The 18 alternate brand names proposed are considered acceptable.